

**REMARKS / ARGUMENTS**

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claims 3, 5, and 6 remain unchanged, and claims 1, 2, and 4 have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. Furthermore, minor amendments have been made to the specification to address minor errors. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention is directed to a method for microbially deactivating items, such as medical, dental, pharmaceutical, veterinary or mortuary instruments and devices, using a liquid microbial deactivation system. Liquid microbial deactivation systems typically operate by exposing the items to be deactivated to a liquid deactivation composition in a reprocessor. In such systems, the items to be deactivated are typically placed within a container that is placed within a deactivation chamber of a reprocessor. During a deactivation cycle in a conventional reprocessor, a liquid deactivation composition is circulated through the container. Following a deactivation cycle, the deactivated items are manually removed from the container. No matter how carefully the items are removed from the reprocessor, the items are exposed to airborne bio-contaminants in the surrounding atmosphere.

The present invention provides a method of both microbially deactivating items in a sealable container and storing the deactivated items for a prolonged period of time in the sealable container. The container includes fluid access ports that have a normally closed position and an open position. The fluid access ports are moveable to the open position by contacting actuating means on the reprocessor. When the container is removed from the reprocessor following a deactivation cycle, the fluid access ports move to, i.e., assume, the normally closed position. In this manner, the container is sealed and the medical instruments contained therein are protected from biological contamination. The items can be stored in the container until they are used again.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a method of microbially deactivating items as presently set forth in the claims, or the advantages thereof.

In response to the Examiner's rejections, claim 1 has been amended to read: "placing said container ... in said cavity ... thereby causing said fluid access ports in said container to move to said open position by contacting actuating means on said reprocessor ...." Claim 1 also indicates that removing said container from said reprocessor causes said fluid access ports to assume said normally closed position.

Claim 4 has been amended to indicate that a *fluid access port is moveable between a normally closed position and an open position*. Claim 4 has also been amended to indicate that placing a container into a reprocessor causes the fluid access port to move to the open position from the normally closed position and that removing the container causes the fluid access port to move to the normally closed position. The claims now define methods for microbially deactivating and storing items in a sealed container, as described above.

The Examiner has rejected claims 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Appropriate corrections have been made by amendment. Accordingly, it is respectfully requested that the Examiner now withdraw the 35 U.S.C. 112, second paragraph, rejection.

The Examiner has also rejected claims 4-6 under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. 103, as being obvious in view of, U.S. Patent No. 6,919,057 to Halstead et al.

Halstead et al. '057 discloses a method for deactivating an endoscope in an automated reprocessor. The reprocessor is dimensioned to receive a container that includes an internal chamber for receiving an endoscope head. The endoscope head is placed within the chamber and the container is placed within the reprocessor. The endoscope includes a cord that extends from the chamber through an outlet. A gasket assembly that is made up of resilient, flexible fins is disposed in the outlet to define a restricted fluid passage around the cord. During reprocessing, a small portion of fluid flows through the fluid passage around the cord. The

slowly leaking liquid insures that all exterior surfaces of the endoscope are in contact with the reprocessing liquid. Thus Halstead et al. '057 does not disclose a *sealable* container dimensioned to receive an entire endoscope. Instead, Halstead et al. '057 discloses a container that is dimensioned to receive only a portion of an endoscope and allows another portion of the endoscope to extend from the container. The container disclosed in Halstead et al. '057 is *not sealable*.

Halstead et al. '057 does not teach, suggest, or show a step of removing a container from a reprocessor, thereby "causing said fluid access port to move to said open position from said normally closed position" as required by claim 4. In this regard, the gasket assembly of the Halstead et al. '057 reference does not have a normally closed position. When an endoscope is not disposed within the container of Halstead et al. '057, the gasket assembly simply defines two open channels between flexible fins. When an endoscope is placed within the container of Halstead et al. '057 and the container is closed, "a flow of reprocessing liquid leaks *out* of the housing through the fin openings insuring that all exterior surfaces are contacted with the cleaning and disinfectant liquids" (column 6, line 67 through column 7, line 3 of Halstead et al. '057). Thus Halstead et al. '057 does not disclose a structure necessary for the steps required by claim 4.

Claims 5 and 6 depend from claim 4. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 4.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead et al. '057. Referring now to claim 1 of the present application as amended, Halstead et al. '057 does not teach, suggest, or show a step of placing a container in a cavity of a reprocessor thereby "causing said fluid access ports in said container to move to said open position by contacting actuating means on said reprocessor ...." In this regard, the outlet cited by the Examiner in Halstead et al. '057 is not moved by contacting the reprocessor.

Further, Halstead et al. '057 does not teach, suggest, or show a step of removing said container from said reprocessor "thereby causing said fluid access ports to assume said normally closed position" as required by claim 1 of the present application. As stated above,

Halstead et al. '057 does not show fluid access ports that have a normally closed position. Thus Halstead et al. '057 does not show a structure necessary to perform a step of "causing said fluid access ports to assume said normally closed position."

The Examiner states that "Halstead discloses a leak test after processing to ensure an endoscope is not damaged during reprocessing ... which would motivate an ordinary artisan to close [the] container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed." Applicants respectfully submit that one skilled in the art would not understand Halstead et al. '057 as disclosing a step of causing fluid access ports to assume a normally closed position when a container is moved from a reprocessor. In this regard, the outlet referred to by the Examiner would continue to have the light guide connector cord extending therethrough and contacting the gasket fins when the container of Halstead et al. '057 is removed from the reprocessor. Thus, removing the container of Halstead et al. '057 from a reprocessor does not cause any change in position of the outlet. Further, as indicated above, the outlet does not have a normally closed position.

In the present application, claims 2 and 3 depend from claim 1. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 1.

In summary, the cited reference does not teach, suggest, or show a method for microbially deactivating items and storing the same as claimed in the present application. Halstead et al. '057 does not teach, suggest, or show a step of causing an access port to move from a normally closed position to an open position by contacting a reprocessor. Further, Halstead et al. '057 does not show a step of causing a fluid access port to move from an open position to a normally closed position upon removal of a container from a reprocessor.

The cited references made of record and not relied upon have also been reviewed. It is respectfully submitted that none of these additional references teaches, suggests, or shows Applicants' invention as defined by the present claims.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters

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that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8630US.

Respectfully submitted,

  
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Mark Kusner, Reg. No. 31,115

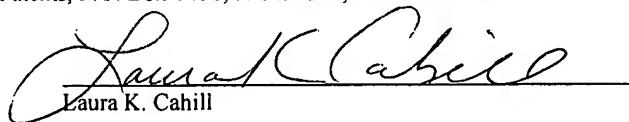
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I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: July 6, 2006

  
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Laura K. Cahill